

More specifically, the Examiner states that “[T]he response asserts that BS124 is a novel polypeptide belonging to the lipocalin family which serve as transfer molecules and provides post filing date support including the reference by Lacazette which was previously considered. As provided in the Office Action mailed September 14, 2000, lipocalin-encoding was not part of the original specification and disclosure. It is noted that utility is required at the time of filing. Therefore, support for the utility after the filing date of the invention does not illustrate that at the time the invention was made the specification provided how to use the claimed invention.” Applicants respectfully traverse this rejection.

35 U.S.C. Section 101 of U.S. Patent Law has two purposes. First, this section defines the categories of invention that are eligible for patent protection (ie., a machine, an article of manufacture, a composition of matter or process or improvement of any of the previous). Second, this section serves to ensure that patents are granted on only those inventions that are useful. Thus, to satisfy the requirements of 35 U.S.C. Section 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is “useful” for some purpose, either explicitly or implicitly.

A claimed invention must have a specific and substantial utility that is credible. Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant’s assertions. *Manuel of Patent Examining Procedure* (8th Edition, August 2001) Section 2107. An applicant only needs to provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. *Id.*

At the time of filing, Applicants’ specification disclosed a specific and substantial utility for the claimed invention. More particularly, the specification states that the polynucleotides, polypeptides or antibodies of the present invention can be used to provide information for detecting, diagnosing, staging, monitoring, prognosticating,

preventing or treating of, or determining the predisposition to, diseases and conditions of the breast, such as breast cancer (see page 23). Applicants submit that BS124 can be used to provide information leading to the detection, diagnosis, staging, monitoring, prognosticating, prevention or treatment of, or determining the predisposition to, breast cancer and that such use is credible.

More specifically, in their previous response, Applicants provided evidence that BS124 is a novel polypeptide belonging to the lipocalin family, which serve as transfer molecules. Applicants also provided a BLAST comparison between BS124 and NM014582, an odorant-binding protein and lipocalin family member. The results of the BLAST comparison showed that BS124 and NM014582 are 97% identical.

Applicants agree with the Examiner that the specification does not disclose that BS124 belongs to the lipocalin family. However, this is not what is important. Rather, what is important is that the evidence Applicants previously submitted demonstrates that lipocalins, such as BS124, play an important role in cancer onset and progression. The fact that BS124 is part of a family of molecules which are known by those of ordinary skill in the art to play an important role in cancer onset and progression lends credibility to Applicants' asserted utility that BS124 can be used to detect, diagnose, stage, monitor, prognosticate, prevent or treat, or determine predisposition to, breast cancer.

Therefore, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Rejection of claims 50-74 under 35 U.S.C. Section 112, first paragraph for lacking a specific, substantial or well established utility. Applicants herewith incorporate by reference their arguments made previously.

Therefore, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Applicants submit that the claims are in condition for allowance.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 01-0025.



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